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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,574	03/31/2004	Sadanandan Bindu	82484	4330
20529	7590	07/12/2006		
NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314				
			EXAMINER AFREMOVA, VERA	
			ART UNIT 1651	PAPER NUMBER

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/813,574	<b>Applicant(s)</b> BINDU ET AL.	
	<b>Examiner</b> Vera Afremova	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 11-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of the Group II, claims 4-10, in the reply filed on 4/27/2006 is acknowledged.

Claims 1-3 and 11-21 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 4/27/2006.

Claims 4-10 are under examination in the instant office action.

### ***Claim Objections***

Claims 4-10 are objected to because of the following informalities:

Accession number(s) of the yeast strain as intended for the claimed invention are missing. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

#### ***Deposit***

Claims 4-10 are rejected under 35 U.S.C. 112, *first paragraph*, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At least some of the claims require one of ordinary skill in the art to have access to specific yeast strain(s) belonging to the species of *Candida versatilis*. Because the

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microorganism is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not clear from the specification or record that the microorganism is readily available to the public. For example: the specific strain EMY 505 is obtained by mutagenization and, thus, its method of making is unpredictable. Moreover, it is uncertain if the parent strain CFR 505 is readily available to the public.

The instant rejection may be overcome by establishing that each microorganism identified is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein. See 37 CFR 1.801-1.809.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or a statement by an attorney of record over his/her signature and registration number, stating that the deposit has been made under the Budapest Treaty and that all restrictions imposed by the depositor on availability to the public of the deposited material will be irrevocably removed upon issuance of the patent would satisfy the deposit requirement. See 37 CFR 1.808.

In order to overcome this rejection the deposit of the strain(s) intended for the claimed invention should be made by applicants in the depository collection that has acquired the status of an International Depository in accordance to the Budapest Treaty and then a declaration

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should be filed that will state that all restrictions will be irrevocably removed upon issuance of the patent.

***Indefinite***

Claims 4-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite and incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: accession number of the yeast strain as intended.

Further, claim 4 is confusing with respect to antecedent basis as related to the use of “mutated strain”, “yeast mutants”, “permeabilized yeast mutants”.

Claim 5 as written appears to lack an antecedent basis for the active step of permeabilizing in the method of claim 4.

Claims 7-9 recite phrases “highest” and “maximum” that are terms of relative degree. The metes and bounds of these terms cannot be determined.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,794,014 (Siren), Quan et al. ("Production of phytase in a low phosphate medium by a novel yeast *Candida krusei*". Journal of Bioscience and Bioengineering. 2001. Vol. 92, No. 2, pages 154-160) and Bindu et al. ("A comparative study on permeabilization treatments for in situ determination of phytase of *Rhodotorula gracilis*". Letters in Applied Microbiology. 1998. 27:336-340).

Claims are directed to a method for reducing phytic acid level in food preparation "Chapathi dough" with an yeast strain belonging to the species of *Candida versatilis* wherein the method comprises step of making "Chapathi dough" by mixing wheat flour, water, salt and the yeast strain(s) and storing the "Chapathi dough" at temperature 10-26°C for 0.5-24 hours, thereby obtaining reduction in the level of phytic acid. Some claims are/are further drawn to the use of the yeast strain(s) cells in a permeabilized form obtained by repeated cycles of freeze-thawing.

The cited patent US 4,794,014 (Siren) discloses a method for reducing phytic acid level in food preparations made from phytate-containing materials (IP6 materials) by using yeast cells as a source of phytase (entire document including col. 3, lines 50-65 and col. 5, lines 22-24). The starting IP6 materials include wheat, wheat bran and wheat flour. In particular example the method for reducing phytic acid level comprises step of making dough by mixing wheat flour, water, salt and the yeast strain(s) and storing the dough, thereby, obtaining reduction in the level of phytic acid (examples 4 and 8). The cited patent teaches that phytate hydrolysis occurs at temperature ranges 20-70°C, thus, including the presently claimed temperatures. The yeast culture that is used as a source of phytase is generic and/or belongs to baker's yeast or

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*Saccharomyces*. Thus, the cited patent is lacking particular disclosure about the use of yeast cells belonging to *Candida*.

However, the reference by Quan et al. demonstrates that yeast cells belonging to *Candida* produce high level of phytase (abstracts) and they are capable of biodegrading phytate in food materials including wheat. In particular example wheat phytate is biodegraded or phytate amounts are considerably reduced within 12 hours (fig. 7 and page 159, col. 1, par. 1).

The cited documents US 4,794,014 (Siren) and Quan et al. demonstrate that yeast cells are source of phytase but they are silent about preliminary treatments of yeast cells that are used as source of phytase in the methods for reducing phytic level in food preparation including wheat and/or wheat-containing dough.

However, the reference by Bindu et al. teaches that yeast cells have tough cell walls, that permeabilization treatments provide for a larger amount of released enzymes and that repeated cycles of freeze-thawing are most efficient for enhancing phytase activity in yeast cell preparations (entire document including abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify method for reducing phytic acid level taught by US 4,794,014 (Siren) by using yeast cells belonging to *Candida* with a reasonable expectation of success in reducing phytic acid level in wheat containing food including dough or "Chapathi dough" because it is well known that yeast cells are used for enzymatic reduction of phytic acid levels in various food and that yeast cells belonging to *Candida* are source of phytase having high enzymatic activity. One of skill in the art would have been motivated to enhance enzymatic

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activity of yeast cell preparations by permeabilizing yeast cells through repeated freeze-thaw cycles for the expected benefits in increasing levels of phytate biodegradation.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

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July 6, 2006

A handwritten signature in black ink, appearing to read 'V. Afremova', with a long horizontal stroke extending to the right.

VERA AFREMOVA

PRIMARY EXAMINER